



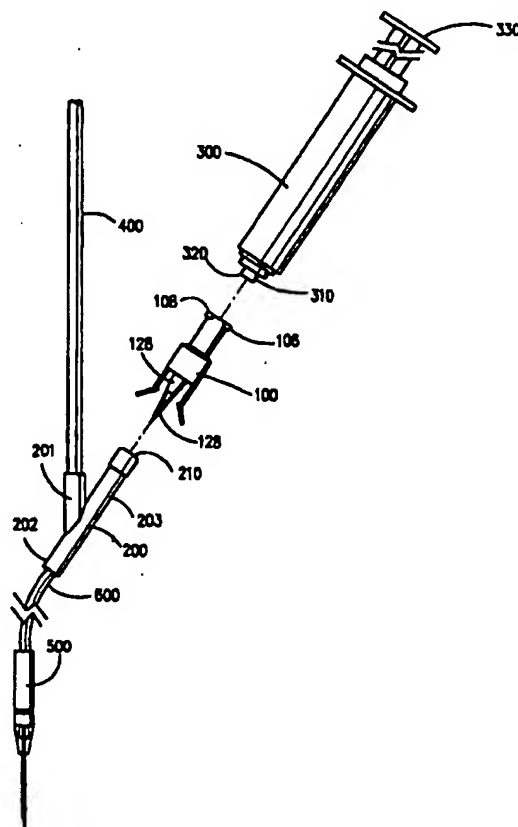
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 35/00	A1	(11) International Publication Number: WO 96/17646 (43) International Publication Date: 13 June 1996 (13.06.96)
(21) International Application Number: PCT/US95/15761 (22) International Filing Date: 5 December 1995 (05.12.95) (30) Priority Data: 08/350,418 6 December 1994 (06.12.94) US (71)(72) Applicant and Inventor: HAINING, Michael, L. [US/US]; 6731 Ashmore Drive, Houston, TX 77069 (US). (74) Agent: MOSELEY, Richard, L.; P.O. Box 630708, Houston, TX 77263 (US).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, LS, MW, SD, SZ, UG). Published <i>With international search report.</i>

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(54) Title: MEDICAL CONNECTOR**(57) Abstract**

A needleless connector for adding medication to a parenteral fluid is provided. In one embodiment (Figs. 1-7), an adapter (100) is provided for securing to a Y connector (200) having a standard puncture pad (210). The adapter (100) includes a cannula (128) for piercing the pad (210) and a valve (130A) is opened by the attachment of a syringe (300). In a second embodiment (Figs. 8-11), the Y connector (200A) itself contains the valve (100A) in lieu of the puncture pad. In a final embodiment (Figs. 12-16), the valve is contained within a universal luer connector adapter (700).



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MEDICAL CONNECTOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to medical connectors used in the introduction of liquids into patients via intravenous solutions. More particularly the invention relates to a needleless connection for use with syringes or other apparatus having a standard luer lock type connection.

2. Related Information

It is a common practice in treating patients, particularly patients who must be cared for under emergency conditions, using medications introduced into the patient intravenously. An intravenous solution, commonly referred to as parenteral fluid, is fed from a container or I.V. bag through a tubing and a catheter which has been inserted into the patient's vein. The catheter is secured to the patient by a strip of adhesive tape. The medication to be administered is generally added to the parenteral fluid through a Y connector in the tubing. The conventional practice has been to inject the fluid using a hypodermic syringe and needle through a sealed entry port in Y connector in the tubing. Generally the seal at the port is a puncture pad of generic latex which for a limited number of uses will reseal itself when a needle is withdrawn.

One problem with this conventional practice is that the needle may be pulled loose from the sealed port very easily. Another problem is needle sticks. From time to time a nurse in attempting to insert the needle into the port will accidentally stick himself or herself with the needle. While there is little risk of infection to the nurse if the needle is new and sterile, the process may be slowed until the needle has been replaced. Lopez, et al in U.S. patent 4,752,292 have presented one solution to the problem.

The connector of Lopez, et al presumes that the needle connector may be easily attached to the source of medication. When measured doses are necessary syringes are more often used and the Lopez connector is not practical.

1 It is an object of the present invention to provide a
2 needleless connector for administering medication through a
3 Y connector of an I.V. system.

4 SUMMARY OF THE INVENTION

5 In its simplest form the present invention comprises a
6 connector adapted to receive a syringe and having a valve
7 to seal the port in place of a puncture pad. The valve
8 comprises a stem with a plug on one end. The stem is
9 biased by a spring such that the plug is normally seated.
10 When a syringe or other apparatus having a male luer
11 connection is engaged with the connector the stem is
12 depressed opening the valve allowing the medication to
13 flow through the connector into the tubing and thus to the
14 patient. The invention may be described as a connector for
15 adding a fluid to a intravenous solution, comprising:

- 16 (a) a valve housing having a seat at one end;
17 (b) a valve stem slidably mounted within said housing
18 having a plug on one adapted to sealably fit into said
19 seat;
20 (c) a spring mounted about said stem to bias said plug
21 against said seat thereby closing said valve; and
22 (d) an actuator means on said stem at the end opposite
23 said plug for moving said stem against said spring bias to
24 move said plug away from said seat thereby opening said
25 valve.

26 Another variation is use of the valve in a universal
27 connector having a male luer connection on one end and a
28 female luer connection on the other. This embodiment
29 allows for use of the valve adaptor for any standard luer
30 connection.

31 BRIEF DESCRIPTION OF THE DRAWING

32 FIG. 1 is a schematic view of a conventional I.V. system
33 and an adapter connector of the present invention and a
34 syringe.

35 FIG. 2 is a perspective view of an adapter connector
36 utilizing the valve of the present invention.

37 FIG. 3 is a plan view in cross section of the adapter
38 connector of FIG. 2.

1 FIG. 4. is a top view of the adapter connector of FIG.
2 2.

3 FIG. 5 is a view of the adapter connector taken along
4 line 5-5 in FIG. 3.

5 FIG. 6 is a bottom view of the adapter connector of FIG.
6 2.

7 FIG. 7 is a plan view in cross section of the adapter
8 connector of FIG. 2 with a syringe attached and the valve
9 open.

10 FIG. 8 is a schematic of an I.V. system with the valve
11 of the present invention included in the Y connector.

12 FIG. 9 is a view of the Y connector of taken along line
13 9-9 in Fig. 8.

14 FIG. 10 is a plan view in cross section of the valve
15 within the Y connector of FIG. 8.

16 FIG. 11 is a plan view in cross section of the valve in
17 the Y connector of FIG. 10 with a syringe attached and the
18 valve open.

19 FIG. 12 is an isometric view of a universal tubing
20 connector utilizing the valve of the present invention.

21 FIG. 13 is a plan view in cross section on the tubing
22 connector of FIG. 12 taken along line 13-13.

23 FIG. 14 is an isometric view of a second embodiment of a
24 universal tubing connector utilizing the valve of the
25 present invention.

26 FIG. 15 is a plan view in cross section of the tubing
27 connector of FIG. 14 taken along line 15-15.

28 FIG. 16 is a top plan view of the tubing connector of
29 FIG. 15 taken along line 16-16.

30 DESCRIPTION OF THE PREFERRED EMBODIMENT

31 For a detailed description of the preferred embodiment
32 the reader is directed to the accompanying figures in which
33 like components are given like numerals for ease of
34 reference.

35 Referring first to FIG. 1 there is shown an intravenous
36 fluid administration system. A first tube 400 is attached
37 by one end to a source of parenteral solution (not shown)
38 and by the opposite end to a Y connector 200. A second

1 tube 600 is connected at a first end to the lower end of
2 the Y connector and at the lower end is connected to an
3 intravenous catheter 500. Since the fluid is administrated
4 by gravity flow the direction up, down, upper and lower
5 have definite meanings.

6 The Y connector is shown to have three connection points
7 or ports. The first port 203 is for receiving the
8 medication which is injected from a syringe 300 and should
9 be angle up from the horizontal to allow injected fluid to
10 flow by gravity into the Y connector and tube 600. The
11 second port 202 is connected to the catheter tube 600. The
12 third connection port 201 is for connection to the
13 parenteral fluid tube 600. The first port 203 extends at
14 an angle from the Y connector 200 such that it is less
15 than 90° from the vertical or from the third port 201.
16 First port 203 is sealed by a puncture pad 210 which in
17 normal systems is pierced by a hypodermic needle mounted on
18 a syringe. In one embodiment of the present invention a
19 connector adapter 100 is provided which includes a cannula
20 128 which pierces the puncture pad 210. Connector adapter
21 also includes standard luer connections 106 and 108 for
22 normal threaded engagement with the syringe. Additionally,
23 as shown in FIG. 2 the connector adapter includes flexible
24 wings 102 and 104 which may engage and lock about the
25 puncture pad. Once the connector adapter 100 is installed
26 there is no need to use a hypodermic needle with the
27 syringe and thus the risk of accidental needle prick is
28 reduced.

29 The puncture pad normally provides for a resealable
30 access to the Y connector. To replace the function of the
31 puncture pad a valve is provided within the connector 100,
32 the details of which are shown in FIG.'s 3-7. Referring
33 now to FIG.'s 3-6 the adapter connector 100 with the valve
34 contained therein is shown. The adapter connector is seen
35 to have a body having two axially aligned cylindrical
36 barrels - larger diameter barrel 138 and smaller barrel 140
37 which are connected by shoulder 150. Extending from the
38 lower end are two flexible wings 102 and 104 each having

1 internal surfaces 122 and 124 respectively for engagement
2 with the puncture pad (not shown in FIG.'s 3-6).
3 Extending centrally from the lower body 138 is cannula 128.

4 The upper end of the connector adapter 100 is shown to
5 have standard luer connections 106 and 108 which engage the
6 luer threads 310 of syringe 300. As shown the syringe 300
7 includes the standard plunger 330 for injecting the fluid
8 through the adapter connector 100 into the Y connector 200.

9 Internally the body is seen to have two axially aligned
10 cylindrical cavities -- upper cavity 118a which is of
11 larger diameter than lower cavity 118b. A channel 120 is
12 provided through cannula which allows for fluid passage
13 from lower cavity 118b and out cannula openings 130a, 130b
14 and 130c.

15 As depicted the valve is shown to be a separate entity
16 which may be assembled first and then inserted into upper
17 body cavity 118a. The valve includes a cylindrical housing
18 142 which fits snugly into upper cavity 118a and is secured
19 there by an appropriate cement. A lower opening 134 in the
20 valve allows fluid communication to lower cavity 118b when
21 the valve is opened. If desired the housing may be have
22 external threads which may engage internal threads of upper
23 cavity 118a. The threaded engagement is not shown.

24 Inside the housing 142 the valve is seen to include a
25 stem 112 which has a plug at the lower end. A spring 110
26 is mounted about the stem 112 and held in place between the
27 bottom of the valve housing and a horizontal bar 126
28 secured to stem 112. Upward movement of the stem is
29 limited by the plug which seats on the underside of the
30 valve housing. The spring 110 provides an upward bias
31 force to keep the plug 114 seated and the valve closed.
32 Stem guide 136 is provided for stability of movement along
33 the axis of the valve.

34 The stem 112 is connected to a "dough nut" actuator 160
35 at the upper end by two support rods 162 and 163. The
36 upper surface of the "dough nut" actuator is flush with
37 the upper surface of the valve housing which in turn is
38 flush with the upper surface of the upper body barrel. The

1 top of the connector adapter is thus even for ease of
2 cleaning.

3 Referring now to FIG. 7 the connector adapter 100 is
4 shown attached to Y connector 200. Cannula 128 is passed
5 through puncture pad 210 and surfaces 122 and 124 have
6 engaged surfaces 230 of puncture pad to secure the
7 connector adapter to the Y connector 200. Threads 330 in
8 syringe engage the luer connection 106 and 108 on upper end
9 of connector adapter and extension 320 on syringe is forced
10 downward against the "dough nut" actuator which in turn
11 forces stem 112 downward to unseat plug 114 and open valve
12 into lower cavity 118b. The flow of fluid may be followed
13 by the arrows.

14 In a second embodiment the valve is placed directly into
15 the first port of the Y connector. This intravenous fluid
16 administration system is shown in FIG. 8. As in the
17 previous embodiment there is shown an intravenous supply
18 tube 400 connected to port 201 of Y connector 200A. A
19 second tube 600 is connected to second port 202 of Y
20 connector and to catheter 500. The first port 203 is
21 provided for administering the medication into the
22 parenteral fluid. As in the previous Y connector the
23 first port 203 extends at an angle from the Y connector 200
24 such that it is less than 90° from the vertical or from the
25 third port 201. The first port 203 is for receiving the
26 medication which is injected from a syringe 300 and should
27 be angle up from the horizontal to allow injected fluid to
28 flow by gravity into the Y connector and tube 600. Instead
29 of the puncture pad the valve 100a is provided. At the end
30 of the first 203 port are luer connections 206 and 208
31 which may be threadedly engaged with the luer connection of
32 the syringe 300 having plunger 330 for injecting the fluid
33 into the Y connector.

34 Referring now to FIG.'s 9 and 10 the construction of the
35 port 203 containing the valve 100a is shown. The details
36 of the valve assembly is the same as in the adapter
37 connector. The valve includes a cylindrical housing 242
38 which fits snugly into upper cavity 218a and is secured

1 there by an appropriate cement. A lower opening 234 in the
2 valve allows fluid communication to lower cavity 218b when
3 the valve is opened. If desired the housing may be have
4 external threads which may engage internal threads of upper
5 cavity 218a. The threaded engagement is not shown.

6 Inside the housing 242 the valve is seen to include a
7 stem 212 which has a plug 214 at the lower end. A spring
8 210 is mounted about the stem 212 and held in place by the
9 bottom of the valve housing and a horizontal bar 226
10 secured to stem 212. Upward movement of the stem is
11 limited by the plug which seats on the underside of the
12 valve housing. The spring 210 provides an upward bias
13 force to keep the plug 214 seated and the valve closed.
14 Stem guide 236 is provided for stability of movement along
15 the axis of the valve.

16 The stem 212 is connected to a "dough nut" actuator 260
17 at the upper end by two support rods 262 and 263. The
18 upper surface of the "dough nut" actuator is flush with
19 the upper surface of the valve housing which in turn is
20 flush with the upper surface of the upper body barrel. The
21 top of the port is thus even for ease of cleaning.

22 Referring now to FIG. 11 the syringe 300 is shown
23 connected to the port 203 of Y connector 200. Threads 330
24 in syringe engage the luer connection 206 and 208 on upper
25 end of connector adapter and extension 320 on syringe is
26 forced downward against the "dough nut" actuator which in
27 turn forces stem 212 downward to unseat plug 214 and open
28 valve into lower cavity 218b. The flow of fluid may be
29 followed by the arrows.

30 Referring now to FIG.'s 12 and 13 the universal adapter
31 connector 700 with the valve contained therein is shown.
32 The adapter connector is seen to have a body having two
33 axially aligned barrels - larger diameter tapered barrel
34 738 and smaller cylindrical barrel 740 which are connected
35 by shoulder 750. Extending centrally from inside the lower
36 body 738 is cylindrical extension 728. Internally of the
37 lower body 738 are standard threads 702 which may engage
38 any standard male luer connection.

1 The upper end of the connector adapter 700 is shown to
2 have standard luer connections 706 and 708 which may be
3 used to engage any standard female luer connection as on a
4 syringe.

5 Internally the body is seen to have two axially aligned
6 cylindrical cavities -- upper cavity 718a which is of
7 larger diameter than lower cavity 718b. A channel 720 is
8 provided through cylindrical extension 728 which allows for
9 fluid passage from lower cavity 118b and out of the
10 connector adapter.

11 As depicted the valve is shown to be a separate entity
12 which may be assembled first and then inserted into upper
13 body cavity 718a. The valve includes a cylindrical housing
14 742 which fits snugly into upper cavity 118a and is secured
15 there by an appropriate cement. A lower opening 734 in the
16 valve allows fluid communication to lower cavity 718b when
17 the valve is opened. If desired the housing may be have
18 external threads which may engage internal threads of upper
19 cavity 718a. The threaded engagement is not shown.

20 Inside the housing 742 the valve is seen to include a
21 stem 712 which has a plug at the lower end. A spring 710
22 is mounted about the stem 712 and held in place by the
23 bottom of the valve housing and a horizontal bar 726
24 secured to stem 712. Upward movement of the stem is
25 limited by the plug which seats on the underside of the
26 valve housing. The spring 710 provides an upward bias
27 force to keep the plug 714 seated and the valve closed.
28 Stem guide 736 is provided for stability of movement along
29 the axis of the valve.

30 The stem 712 is connected to a "dough nut" actuator 760
31 at the upper end by two support rods 762 and 763. The
32 upper surface of the "dough nut" actuator is flush with
33 the upper surface of the valve housing which in turn is
34 flush with the upper surface of the upper body barrel. The
35 top of the connector adapter is thus even for ease of
36 cleaning.

37 Finally FIG.'s 14-16 depict a second embodiment of the
38 universal tubing connector is shown. The connector is

1 essentially the same as that shown in FIG.'s 12 and 13
2 except that a rubber cover 740A is provided over the barrel
3 740 and the end of the barrel. A pre-cut slit 740B is
4 provided in the rubber cover 740A over the end of the
5 barrel for insertion the luer connector. The remaining
6 reference numeral are the same as in FIG.'s 12 and 13.

7 The connector adapter is designed to be used with
8 existing Y connectors while the second embodiment is
9 preferred with the valve being integrated within the Y
10 connector. The third connector adapter is designed to be
11 used with any luer connection. In addition, the rubber
12 cover shown in FIG.'s 14-16 may be placed over the luer
13 receiving end of any of the connectors shown in the
14 figures.

15

The invention claimed is:

1. A medical connector comprising:

(a) a cylindrical body having an upper cavity and a lower cavity, said upper cavity having a valve seat at the lower end;

(b) a valve stem slidably mounted within said upper cavity having a plug on one adapted to sealably fit into said seat;

(d) a spring mounted about said stem to bias said plug against said seat thereby closing said valve;

(e) an actuator means on said stem at the end opposite said plug for moving said stem against said spring bias to move said plug away from said seat thereby opening said valve;

(f) a cylindrical extension axially mounted on the lower end of said body defining an annular space between the outer surface of said extension and the inner surface of said lower cavity; and

(g) internal threads on the inner surface of said lower cavity for engagement with a male luer connector.

2. The medical connector of claim 1 further comprising a male luer connection on the upper end of said body for engagement with a female luer connector.

3. The medical connector of claim 1 further comprising a rubber cover over said upper body covering said actuator means.

4. The medical connector of claim 3 further comprising a slit in said rubber cover directly over said actuator means.

5. A connector for adding medication from a syringe to an intravenous fluid comprising:

(a) a hollow cylindrical body having

(i) a first port on one end for adding medication to the intravenous fluid,

(ii) a second port on the other end for connection to a catheter which is inserted into the vein of a patient, and

(iii) a third port intermediate said first and

second ports for attachment to a intravenous fluid source;

(b) a luer connection on the open end of said first port;

(c) a valve housing secured within said first port and having a seat at one end;

(d) a valve stem slidably mounted within said housing having a plug on one end to sealably fit into said seat;

(e) a spring means mounted about said stem to bias said plug against said seat thereby closing said valve; and

(f) an actuator means on said stem at the end opposite said plug for moving said stem against said spring bias to move said plug away from said seat thereby opening said valve when a syringe is threadedly connected to said luer connection.

6. The connector of claim 5 further comprising a rubber cover over said first port.

7. The connector of claim 6 further comprising a self reclosing slit in the end of said rubber cover.

8. A connector for adding medication from a syringe to an intravenous fluid comprising:

(a) a hollow cylindrical body having

(i) a first port on one end for adding medication to the intravenous fluid,

(ii) a second port on the other end for connection to a catheter which is inserted into the vein of a patient, and

(iii) a third port intermediate said first and second ports for attachment to a intravenous fluid source;

(b) a luer connection on the open end of said first port;

(c) a valve housing secured within said first port and having a seat at one end;

(d) a valve stem slidably mounted within said housing having a plug on one end to sealably fit into said seat;

(e) a spring means mounted about said stem to bias said plug against said seat thereby closing said valve;

(f) an actuator means on said stem at the end opposite said plug for moving said stem against said spring bias to

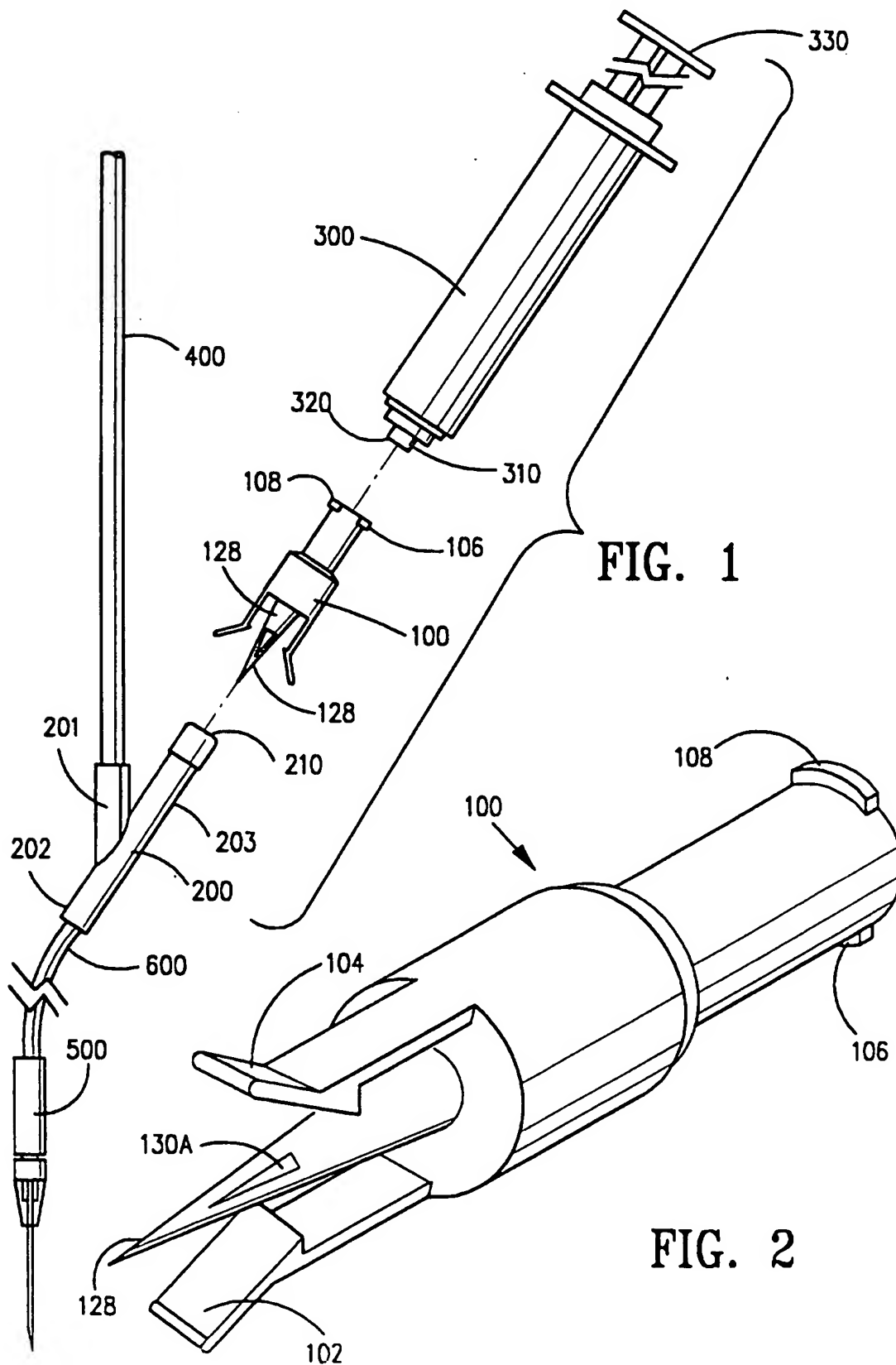
move said plug away from said seat thereby opening said valve when a syringe is threadedly connected to said luer connection;

(h) a rubber cover over said first port; and

(i) a self reclosing slit in the end of said rubber cover.

9. The connector according to claim 1 further comprising a pair of flexible wings mounted on the outer periphery of the body to engage the end surface of a puncture pad and secure the connector thereon.

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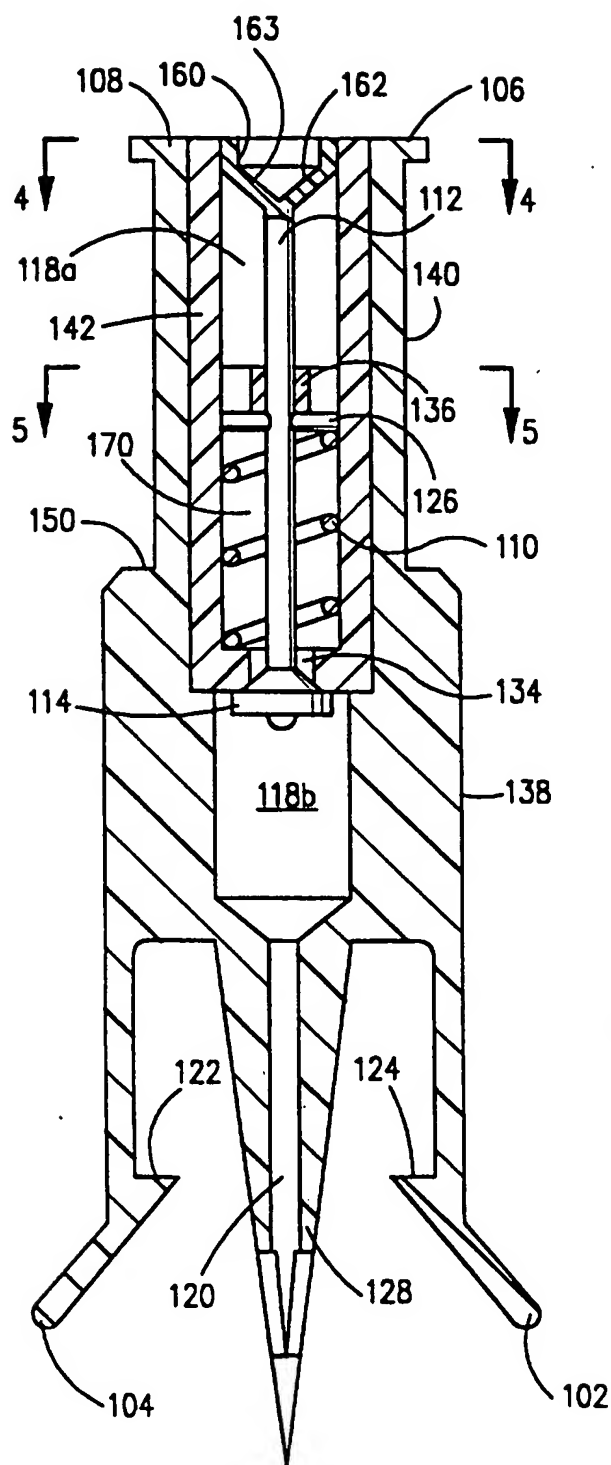


FIG. 3

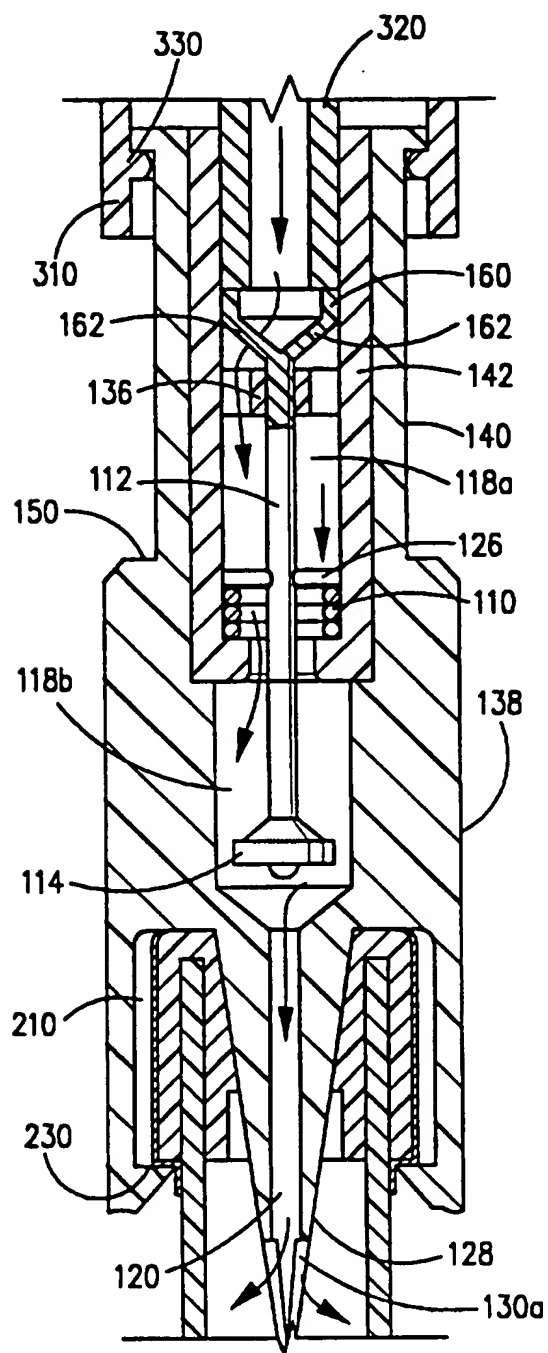


FIG. 7

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FIG. 4

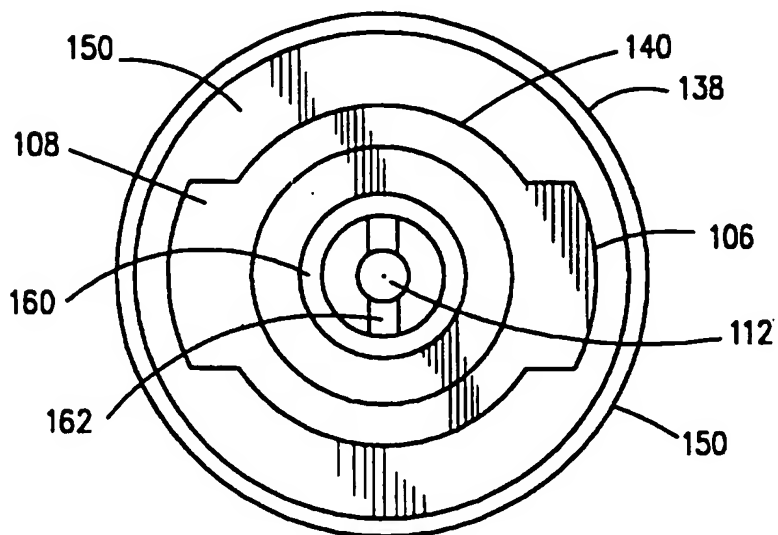


FIG. 5

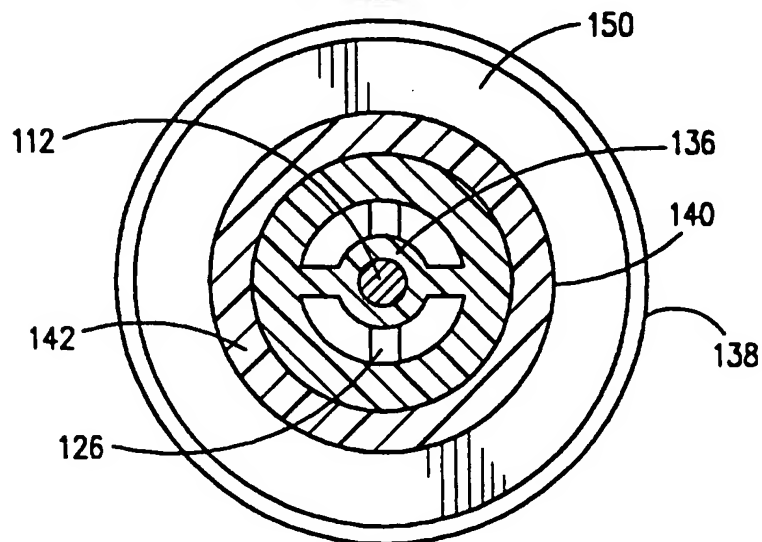
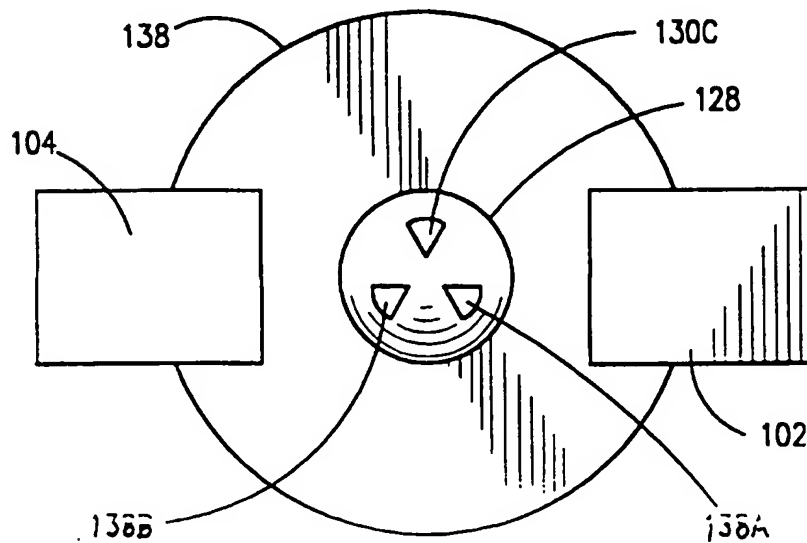
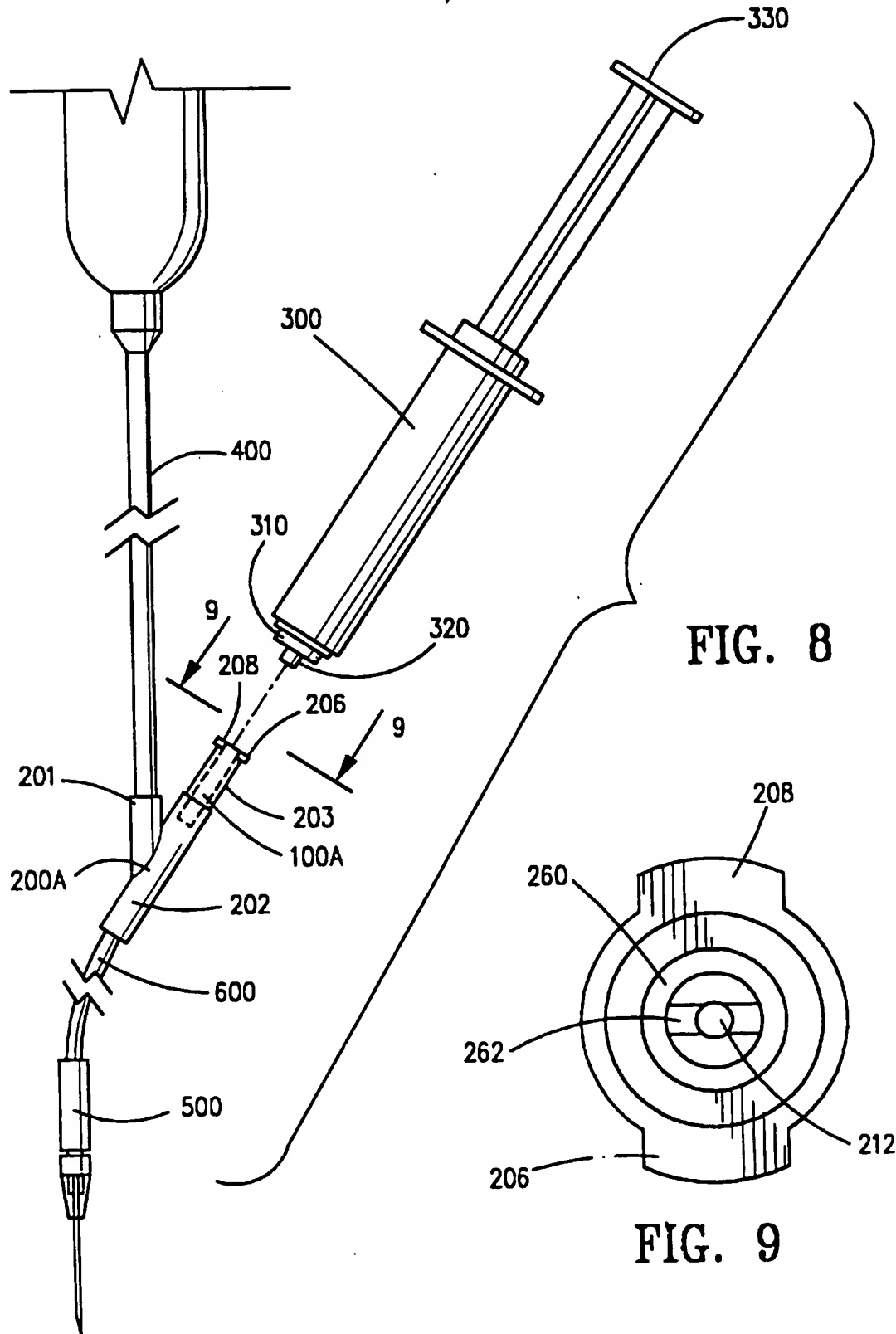


FIG. 6



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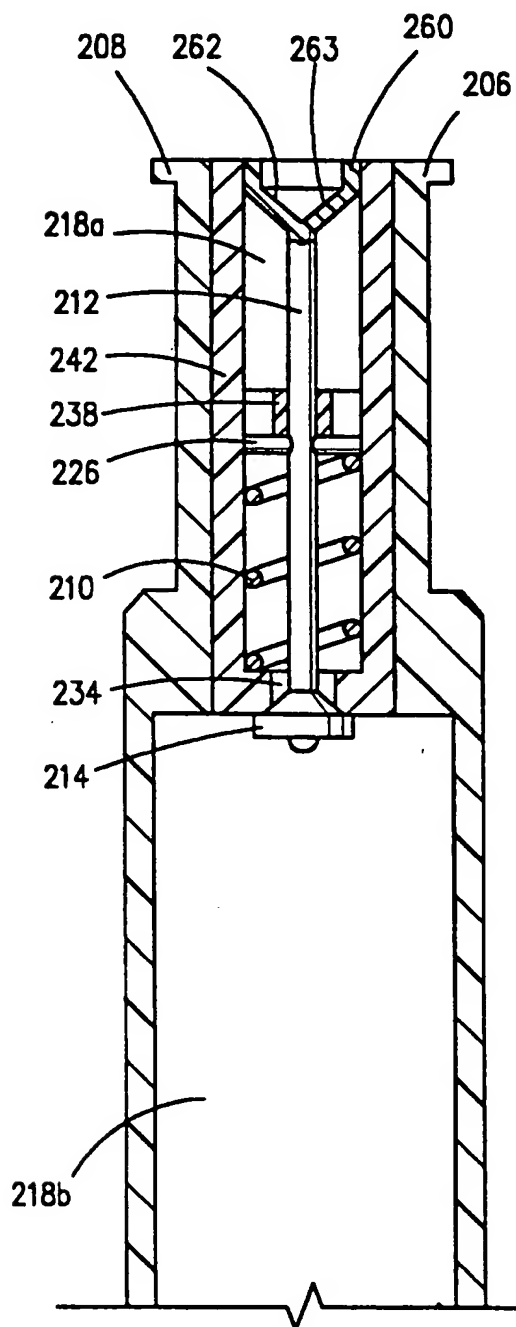


FIG. 10

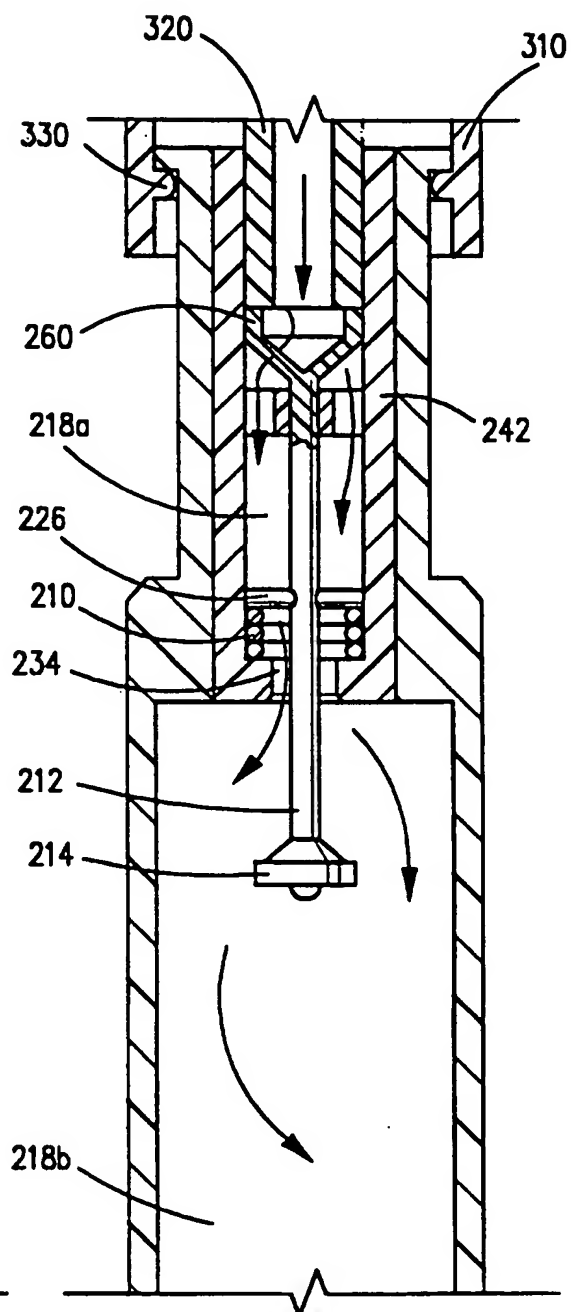


FIG. 11

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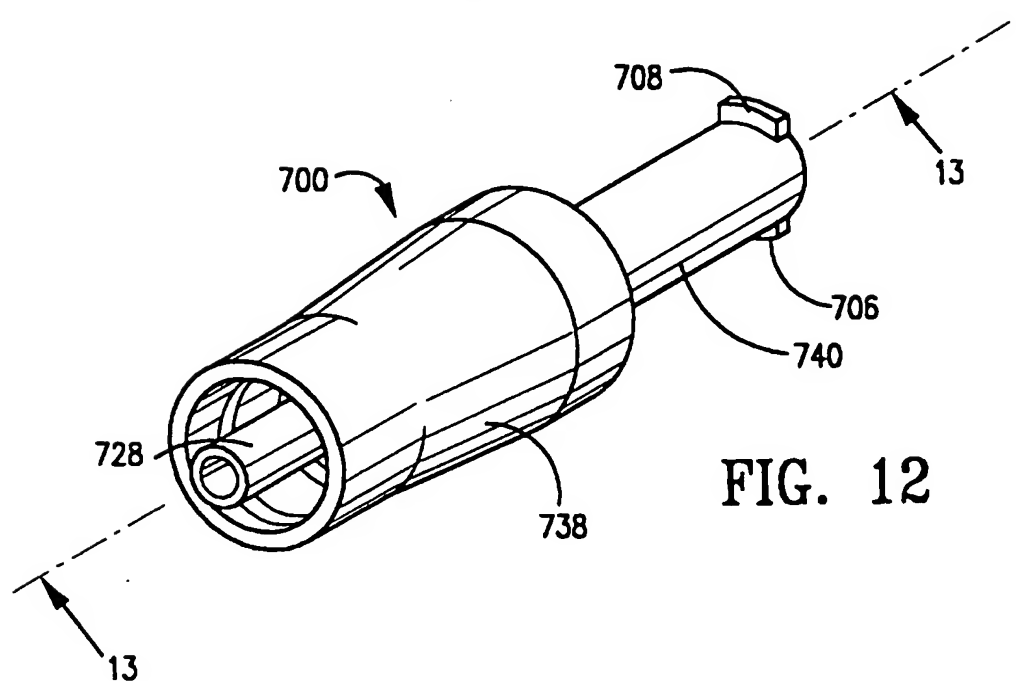


FIG. 12

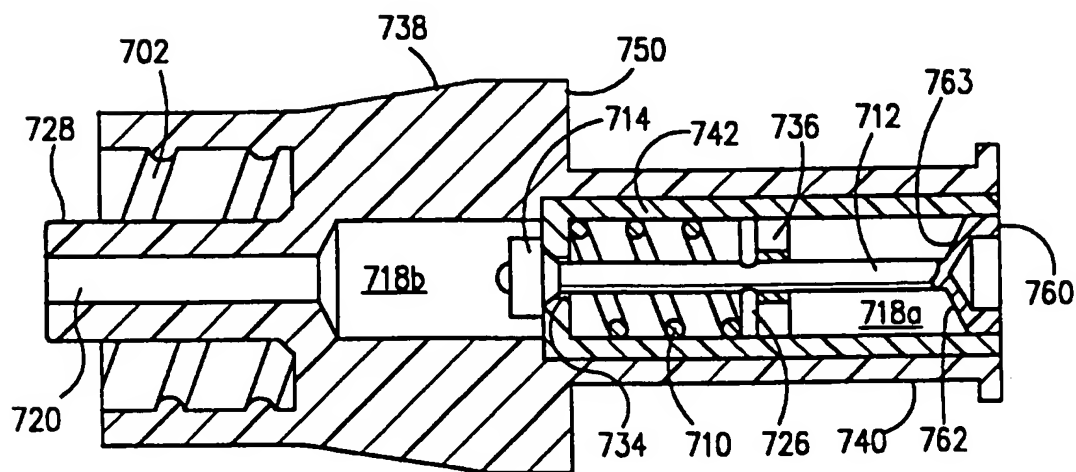


FIG. 13

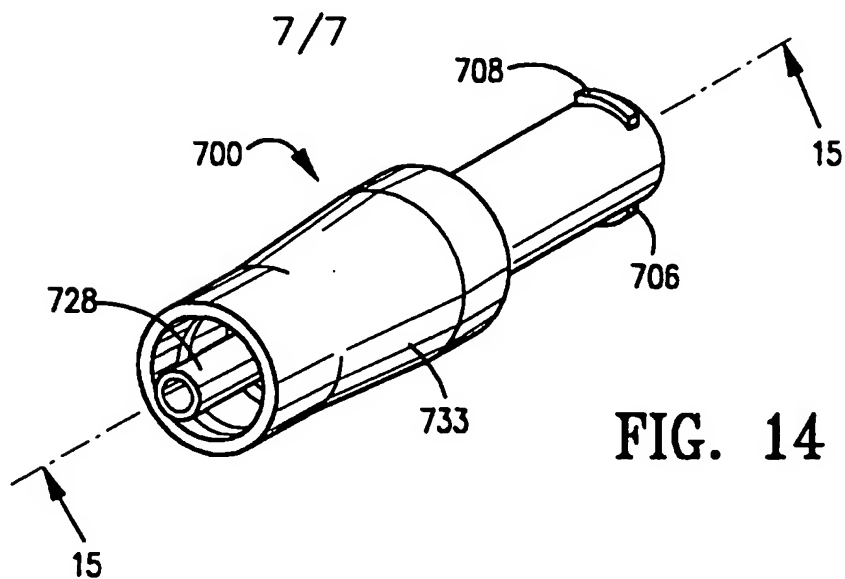


FIG. 14

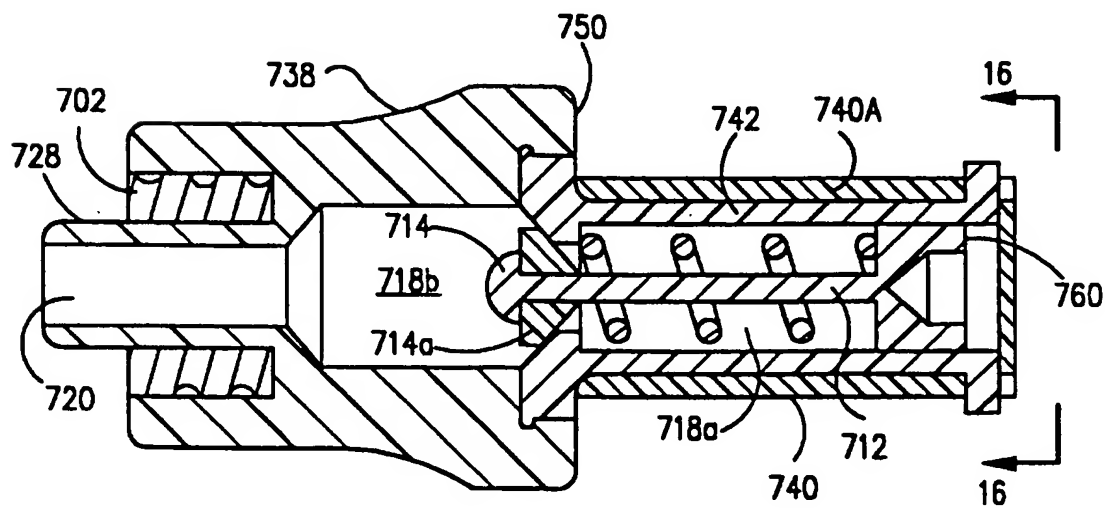


FIG. 15

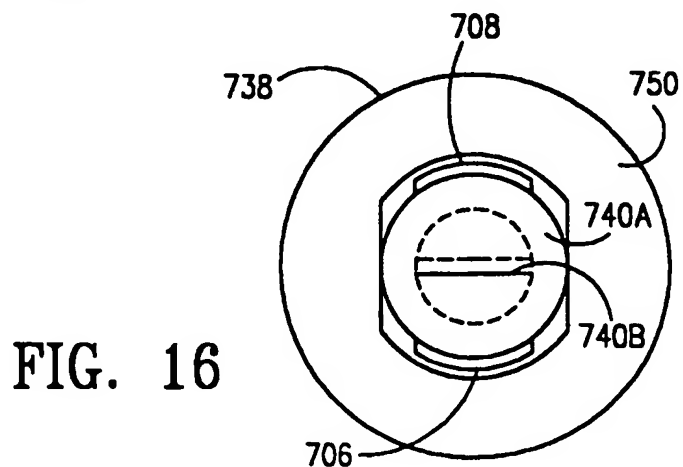


FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/15761**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : A61M 35/00

US CL :251/149.6; 604/86, 249

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 251/149.1, 149.6, 149.7; 604/82, 83, 86, 88-91, 246, 249, 280, 283, 284, 905

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,163,922 (MCELVEEN, JR. ET AL.) 17 November 1992, see entire document.	1, 2, 5
Y	US, A, 4,506,691 (TSEO) 26 March 1985, see entire document.	1, 2, 5
A	US, A, 5,041,087 (LOO ET AL.) 20 August 1991, see entire document.	1-9
A, P	US, A, 5,401,245 (HAINING) 28 March 1995, see entire document.	1-9

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	* T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* A document defining the general state of the art which is not considered to be part of particular relevance	* X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search

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